

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Effect of family- centered empowerment program on self-efficacy in adolescents with thalassemia major

Protocol summary

Summary

It is quasi-experimental study. The aim of this study was to determine the effect of family centered empowerment program on self-efficacy in adolescents with thalassemia major. The research environment is specific diseases Aboureihan center in Bandar Abbas. Teens (12-18 years) with thalassemia major and active members of their family, community, and in this study, samples are adolescents with thalassemia major aged (12-18) years with a family member who Are eligible. Sampling available. The control group had 35 people that will be removed from the intervention group. Tools put at the control group and without intervention, tools again after 1.5 months they will be completed. 35 patients in the intervention group selected that will have the inclusion criteria. After confirming the validity content of teaching, Intervention as a family-centered empowerment programs in four structures of knowledge, self-efficacy, training participation and evaluation will be conducted. Inclusion criteria included: A partnership a family member with patient, have at least read and write to the patient and Active member of the family and Ability to participate in the program. Exclusion criteria included: Unwillingness of the patient and an active member of family to participate in the study and Unwillingness of the patient and an active member of family to participate in Problem solving and training sessions. It's expected that this program to be one of the nursing interventions used to increase the efficacy in patients with thalassemia major.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201407211788N8**

Registration date: **2015-06-01, 1394/03/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-06-01, 1394/03/11

Registrant information

Name

Leili Borimnejad

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences, research vice chancellor

Expected recruitment start date

2014-03-30, 1393/01/10

Expected recruitment end date

2014-09-21, 1393/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of family- centered empowerment program on self-efficacy in adolescents with thalassemia major

Public title

The effect of family centered empowerment program on self-efficacy

Purpose

Other

Inclusion/Exclusion criteria
 Inclusion criteria included: • A partnership a family member with patient • have at least read and write to the patient and Active member of the family • Having Medical records in center • Lack of specific mental health problem • Ability to participate in the program Exclusion criteria included: • Unwillingness of the patient and an active member of family to participate in the study. • Unwillingness of the patient and an active member of family to participate in Problem solving and training sessions.

Age
 From **81 years** old to **75 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **70**

Randomization (investigator's opinion)
 Not randomized

Randomization description

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Keshavarz Blvd, Qods St., Central University

City

Tehran

Postal code

Approval date

2014-01-14, 1392/10/24

Ethics committee reference number

92/130/2376/3

Health conditions studied

1

Description of health condition studied

Beta Thalassemia

ICD-10 code

D56.1

ICD-10 code description

Cooley anaemiaSevere beta thalassaemia
 Thalassaemia:•intermedia

Primary outcomes

1

Description

general self- efficacy

Timepoint

Before the intervention, after the intervention

Method of measurement

Schwarzer General Self-Efficacy Scale(GSE-10)

2

Description

Disease-related self-efficacy

Timepoint

Before the intervention, after the intervention

Method of measurement

Sickle Cell Self-Efficacy Scale(SCSES)

Secondary outcomes

empty

Intervention groups

1

Description

Control group: these people are selected from specific diseases Aboureiha center in Bandar Abbas. We give them the tools to complete their And 1.5 months later, without any intervention so that only routine nursing care received, the tools will be completed.

Category

Other

2

Description

Intervention Group: Sampling available. these people are selected from specific diseases Aboureiha center in Bandar Abbas. After obtaining the written consent of the subjects in the experimental group, pre-test will be conducted. Empowering patients based on four constructs: knowledge, self-efficacy, training participation and evaluation. The first step (perceived threat) empowerment program will try to increase their knowledge through booklets and group discussion. Thus, based on the number of teenagers, they were divided into groups of 3-5 people. Empowerment programs to suit the needs of the participants every two weeks, three sessions, 30-45 minutes. At this stage, Participants were asked to transfer educational materials that have learned to bring a family member. Therefore, educational pamphlets given to them To be an active member of

family. That study and questions that come to mind, write in a sheet and the next meeting, deliver researcher. Therefore, the next meeting will review all comments. . During the second step (self-efficacy), aims to improve patients' self-efficacy through group discussion and collaborative problem solving. In the third step (educational participation), will try to increase the efficacy through educational participation. . As mentioned in the first step, Participants were asked to Information obtained from meetings and educational pamphlets, available to active members of their family. So to ensure we achieve this goal, the participants requested that with active member be present at the meeting and participate in group discussions and question and answer. The fourth step is evaluation done in two stages. The first stage involve asking two questions orally at the beginning of each session and The second stage is the final evaluation that instruments will be completed again by the sample.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

The specific diseases Aboureihan center

Full name of responsible person

belgheis Sheibani

Street address

Bandar Abbas. koi shafa-The specific diseases Aboureihan center

City

Bandar Abbas

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Yunesian

Street address

Ghods Street, Tehran, Keshavarz Boulevard, Central Building

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Leili Borimnejad

Position

PHD/ Assistant Training

Other areas of specialty/work

Street address

Vali Asr (AS) -Higher from Vanak Square - Rashid Street Yasami Faculty of Nursing and Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Leili borimnejad

Position

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Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty